Major Data Gaps for Moss Buster (EPA File Symbol No. 84316-R) Which Preclude a Full Review.

1. No product chemistry studies/data

2. CSF is unacceptable.

   a. Specific amounts of carvacrol and thymol, and their certified limits, are not listed
   b. No CAS Nos. for any ingredient listed

3. Inadequate Waiver Justifications

   General Inadequacies: The registrant claims that no data are available for Oregano/Oregano Oil, but failed to search for toxicological data on the major components of Oregano Oil (Carvacrol and Thymol). An extensive toxicity database is available in NLM HSDB on both components. The registrant should relate the toxicity values here (as well as others that may be available) with the expected exposure (and route of exposure) resulting from a spray application of the product. The use of a spray product will likely result in exposure via dermal, ocular, and inhalation exposure. Therefore, waiver rationales stating that the "product is limited to soil applications by spray" are not adequate to support the waiver request.

   NOTE: According to NLM HSDB, the major component of oregano oil carvacrol) has a human LD50 =50-500 mg/kg (Tox II) and caused sever dermatitis in human patch tests and was severely irritating when applied undiluted to intact or abraded rabbit skin. It had pronounced mutagenicity in 5 strains of S. typhimurim.

   NOTE: According to Biopesticide RED Fact Sheet, Thymol, at high concentrations is corrosive to skin and eye, and is a sensitizer. Toxic to aquatic invertebrates.

   Much of the waiver information is based on exposure information for dried oregano, not oregano oil.

   Information used to support waiver request for Acute Oral LD50 testing is repeated inappropriately for other routes of exposure.

   NOTE: The FDA GRAS designation can only be used to support the Acute Oral LD50 waiver request. Registrant must better justify how Acute oral LD50 information can be used to support Acute Dermal LD50 waiver.

   The registrant also failed to distinguish between the TGAI and the End-use product when crafting the waivers. Since the EP is apparently is only 0.9% Oregano Oil, it is unclear how the waiver requests (apparently for the TGAI) address the data requirements for the EP.

The BPPD reviewer concurs with the contractor reviewer in that the waiver requests for acute oral toxicity and 90-day oral toxicity are acceptable based on a lack of oral exposure.

The BPPD reviewer DOES NOT concur with the contactor reviewer regarding waiver requests for acute dermal toxicity, 90-day dermal toxicity, acute dermal irritation, and skin sensitization. The registrant did not demonstrate that there would be no exposure via these routes of exposure. Furthermore, the NLM HSDB data base for carvacrol and thymol indicates that both components may have toxic properties via these routes of exposure.

The registrant did not adequately demonstrate lack of toxicity or lack of exposure to non-target organisms via use of the end-use products. Spray application to the soil does not necessarily preclude exposure (either direct or indirect) to non-target taxa. Furthermore, the registrant did not demonstrate that the oregano oil or its components degraded rapidly.